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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/013,077	01/26/1998	JEFFREY L. NAUSS		2904

7590 07/22/2002  
NASH & TITUS, LLC  
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EXAMINER

CELSA, BENNETT M

ART UNIT PAPER NUMBER

1627

DATE MAILED: 07/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

file copy

## Office Action Summary

Application No.  
09/013,077

Applicant(s)

Naus et al.

Examiner

Bennett Celsa

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1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on Mar 20, 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 15, 18, 21-23, 25, 26, 48, and 49 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 15, 18, 21-23, 25, 26, 48, and 49 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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## **DETAILED ACTION**

### ***Continued Prosecution Application***

1. The request dated 3/20/02 in paper no. 31 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/013,077 is acceptable and a CPA has been established. An action on the CPA follows.

### ***Status of the Claims***

Claims 15, 18, 21-23, 25, 26, 48 and 49 are currently pending.

2. It is noted that Group II below resulted because claim 23 (as amended to refer to 13 amino acid peptides) is improperly dependent upon claim 15 with respect to the 16 amino acid peptide of seq. Id. 3, since it fails to further limit. It is also noted that applicant has failed to provide support for this new limitation with regard to seq id 3..

### ***Election/Restriction***

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 15, 21-23, 25, 26, 48 and 49 (All in part) drawn to a composition *comprising* a 16 amino acid peptide of seqId 3 classified in class 514, subclass 13
  - II. Claim 23 (in part), drawn to a composition comprising a 13mer peptide of the 16 amino acid peptide of seq. Id. 3, classified in class 514, subclass 14.
  - III. Claims 15, 21-23, 25, 26, 48 and 49 (All in part) drawn to a composition *comprising* a 13 amino acid peptide of seqId 6, classified class 514, subclass 14

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- IV. Claims 15, 21-23, 25,26, 48 and 49 (All in part) drawn to a composition *comprising* a 13 amino acid peptide of seq.Id 5, classified in class 514, subclass 14
- V. Claims 15, 21-23, 25,26, 48 and 49 (All in part) drawn to a composition *comprising* a 13 amino acid peptide of seqId12, classified in class 514, subclass 14
- VI. Claims 15, 21-23, 25,26, 48 and 49 (All in part) drawn to a composition *comprising* a 13 amino acid peptide of seqId11, classified in class 514, subclass14
- VII. Claims 15, 21-23, 25,26, 48 and 49 (All in part) drawn to a composition *comprising* a 13 amino acid peptide of seqId10, classified in class 514, subclass 14
- VIII. Claims 15, 21-23, 25,26, 48 and 49 (All in part) drawn to a composition *comprising* a 13 amino acid peptide of seqId 9, classified in class 514, subclass 14
- IX. Claim 18 (in part) drawn to a method of use a composition *comprising* a 16 amino acid peptide of seq. Id. 3 to elicit an immune response, classified in class 424, subclass 184.1+
- X. Claim 18 (in part), drawn to a method of using a composition comprising a 13mer peptide of the 16 amino acid peptide of seq. Id. 3 to elicit an immune response, classified in class 424, subclass 184.1+
- XI. Claim 18 ( in part), drawn to a method of using a composition *comprising* a 13 amino acid peptide of seq. Id. 6 to elicit an immune response, classified in class 424, subclass 184.1+

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- XII. Claim 18( in part), drawn to a method of using a composition *comprising* a 13 amino acid peptide of seq. Id. 5 to elicit an immune response, classified in class 424, subclass 184.1+
- XIII. Claim 18 ( in part), drawn to a method of using a composition *comprising* a 13 amino acid peptide of seq. Id. 12 to elicit an immune response , classified in class 424, subclass 184.1+
- XIV. Claim 18 ( in part), drawn to a method of using a composition *comprising* a 13 amino acid peptide of seq. Id. 11 to elicit an immune response, classified in class 424, subclass 184.1+.
- XV. Claim 18(in part), drawn to a method of using a composition *comprising* a 13 amino acid peptide of seq. Id. 10 to elicit an immune response, classified in class 424, subclass 184.1+
- XVI. Claim 18 ( in part) , drawn to a method of using a composition *comprising* a 13 amino acid peptide of seq. Id. 9 to elicit an immune response, classified in class 424, subclass 184.1+
4. The inventions are distinct, each from the other because of the following reasons:
5. The peptide containing compositions of Groups I-VIII are independent and/or patentably distinct compositions since these compositions comprise peptides which are structurally distinct due to differences in amino acid composition and length, possess different physicochemical properties, are capable of separate manufacture and/or use; which will result in different and

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separately burdensome bibliographic, structural and sequence searches in manual and computer, patent and literature databases. Additionally, these different peptide sequences lack any common core structure necessary to elicit a common activity (e.g. improper Markush groups) and will require separate issues under 35 USC 112, first paragraph (e.g. new matter, enablement and/or utility) and will face different issues regarding priority under 35 USC 120 (e.g. CIP priority over several applications).

6. The methods of Groups IX-XVI are drawn to independent and/or patentably distinct methods of eliciting an immune response since these methods employ independent and/or patentably distinct peptides to be administered in vivo to an animal. Additionally, these methods will require the consideration of separate issues under 35 USC 112, first paragraph (e.g. new matter, enablement and/or utility) and will face different issues regarding priority under 35 USC 120 (e.g. CIP priority over several applications).

7. Inventions (I-VIII in the alternative) and (~~IX~~X-XVI in the alternative) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product since multiple peptides of seq. Id 3, 6, 5, 12, 11, 10 and 9 elicit immune responses. Additionally, the product as claimed (e.g. Id 3, 6, 5, 12, 11, 10 or 9) can be used in a materially different process

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of using that product, such as the production of hybridomas, harvesting antibodies, cellular therapy etc. See e.g. specification page 6, especially lines 1-1-15.

8. It is noted that in accordance with U.S. practice, upon the allowance of a composition within an elected composition invention (e.g. any one of Groups I or II ... VIII), the Examiner will *consider rejoinder of the corresponding* method of use claim (e.g. Group IX or XI ... XVI, as applicable) which are commensurate in scope to the allowed subject matter pursuant to MPEP 821.04 Rejoinder

9. Because these inventions are distinct for the reasons given above and

- a. have acquired a separate status in the art as shown by their different classification;
- b. the manual and computer sequence, structure, bibliographic and classification searches in patent and literature databases which are required for Group I is not required for Group II; and
- c. because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

**General information regarding further correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Celsa whose telephone number is (703) 305-7556.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe McKane (art unit 1627), can be reached at (703)308-0570.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Bennett Celsa (art unit 1627)  
July 17, 2002

BENNETT CELSA  
PRIMARY EXAMINER

